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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,473	09/26/2001	Terry A. Guinan	P1046 US	2802
7590 02/18/2004				
Medtronic AVE, Inc. 3576 Unocal Place Santa Rosa, CA 95403		EXAMINER BAXTER, JESSICA R		
		ART UNIT PAPER NUMBER		
		3731 13		
DATE MAILED: 02/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,473

Applicant(s)

GUINAN ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 6, 7, 10, 11, 12, 13, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,056,906 to Werneth et al.

Regarding claims 1, 2, 6, 7, 10 and 11, Werneth discloses a stent delivery catheter comprising an elongate shaft (shaft 70) having a lumen (inflation lumen 65) therethrough; a balloon (balloon 35) mounted about a distal region of the shaft and being in fluid communication with the lumen, the balloon having a flexible wall, an intermediate body, proximal and distal cones, proximal and distal ends attached to the shaft (FIG. 2), and a first and second circumferential C- shaped groove (55) formed of the balloon wall adjacent a transition between the intermediate body and one of the proximal and distal cones wherein said first circumferential groove is present when the balloon is in an inflated state and a deflated state (FIG. 3 and 6); and a balloon-expandable stent (stent 20) mounted about the intermediate body of the balloon.

Regarding claims 4, 12, 13 and 18, Werneth discloses that the at least one circumferential groove is at least partially filled with a flexible material that is adhered to the balloon (Column 6 line 66-Column 7 line 2).

Regarding claim 15, Werneth discloses a method of making a stent delivery catheter comprising providing a catheter having an elongate shaft (shaft 70) having a lumen

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(inflation lumen 65) therethrough; mounting a balloon (balloon 35) about a distal region of the shaft and being in fluid communication with the lumen, the balloon having a flexible wall, an intermediate body, proximal and distal cones, proximal and distal ends attached to the shaft (FIG. 2), and at least one circumferential groove (55) formed of the balloon wall adjacent a transition between the intermediate body and one of the proximal and distal cones wherein said at least one circumferential groove is present when the balloon is in an inflated state and a deflated state (FIG. 3 and 6); collapsing the balloon around the catheter shaft; and mounting a balloon-expandable stent (stent 20) about the intermediate body of the balloon (Column 5 line 35 –Column 6 line 4).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werneth et al. '906 in view of U.S. Patent No.6,254,608 to Solar.

Werneth discloses the claimed invention except for the flexible material comprising a foamed material. Solar teaches that a foamed material is used for bonding the stent to the catheter to allow the stent to become embedded in the balloon in order to protect the anatomical passageways during delivery of the stent and prevent the stent from slipping without the use of a protective sheath (Column 3 line 44 – Column 4 line 2 and Column 5 lines 20-24). It would have been obvious to one having ordinary skill in the art at the time

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the invention was made to provide the balloon catheter of Werneth with the foamed material of Solar in order to protect the anatomical passageways during stent delivery and prevent the stent from slipping off the balloon without the use of a protective sheath.

5. Claims 3, 8, 9, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werneth et al. '906 in view of U.S. Patent No. 6,293,959 to Miller et al.

Werneth discloses the claimed invention except for the balloon having a deflated profile where the distal and proximal cones have a larger deflated profile than the intermediate body. Miller teaches that the enlarged proximal and distal cones are provided to provide a nest portion for the stent so that friction is minimized and adverse contact between the ends of the stent and the vessel wall is minimized (Column 4 lines 36-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon of Werneth with the enlarged proximal and distal cones of Miller in order to provide a nest portion for the stent in order to minimize friction and adverse contact between the stent ends and the vessel wall.

Response to Arguments

6. Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JRB
jrb

Jessica R Baxter
Examiner
Art Unit 3731


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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